***In re National Prescription Opiate Litigation*: MDL 2804**
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Opposition to Defendant Janssen Pharmaceutical Inc.'s Motion for Summary Judgment (DKT 1776-3)

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Issue 1: Has Janssen sustained its burden of showing entitlement to summary judgment dismissal of Plaintiffs' marketing claims?

Answer: No. Plaintiffs offer considerable evidence of Janssen's fraudulent marketing of its branded opioids, Duragesic and Nucynta. Additionally, from 1997 through 2012, Janssen paid massive sums of money to pain advocacy organizations and to doctors to promote opioid use throughout America, and in Plaintiffs' counties. Janssen promoted the falsehood of "under-treatment of pain" in America and fomented the notion that opioids were associated with a low abuse potential. Janssen's argument that unbranded marketing after 2008 came too late to be a cause of Ohio's opioid crisis is absurd: Janssen's marketing certainly contributed to the continuation and growth of that crisis. Further, Janssen actively targeted Ohio with its false branded and unbranded marketing messages resulting in increased prescribing of opioids generally, and the increased incidences of addiction, overdose and death that followed.

Issue 2: Has Janssen sustained its burden of showing that it is entitled to summary judgment dismissal because it utilized third party marketing messages and opioid treatment guidelines that are purportedly protected by the First Amendment?

Answer: No. It is well settled law that, "[u]ntruthful speech, commercial or otherwise, has never been protected for its own sake." *Va. State Bd. Of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976).

Issue 3: Has Janssen sustained its burden of showing that it is entitled to summary judgment dismissal of Plaintiffs' Controlled Substance Act claims?

Answer: No. Plaintiffs have offered considerable evidence that its SOMs system fell far short of meeting its obligations under the CSA. The fact that the DEA did not cite Janssen for violations of its SOMs duties during inspections, is not evidence of compliance. *Masters Pharm., Inc. v. Drug Enforcement Admin.*, 861 F.3d 206, 224-25 (D.C. Cir. 2017).

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' OPPOSITION TO DEFENDANT JANSSEN PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT (DKT. #1776-3)

July 31, 2019

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I. INTRODUCTION

Defendants Johnson & Johnson ("J&J") and its subsidiary, Janssen Pharmaceuticals, Inc. ("Janssen"), were primary actors in the cast of characters whose conduct resulted in the current opioid crisis. As early as 1994, Janssen began marketing its fentanyl patch, Duragesic, to non-cancer patients for treatment of chronic pain, effectively broadening its indications. Numerous Plaintiff witnesses testified regarding their experience with misuse of that patch. Nonetheless, after Duragesic's exclusivity expired, Janssen introduced another opioid product, Nucynta (and the extended release version, Nucynta ER), and marketed those products heavily within the bellwether jurisdictions.

Notably, J&J avoided filing its own separate summary judgment motion in an effort to cast its subsidiary, Janssen, as a small market share pharmaceutical manufacturer that purportedly had nothing to do with the existing opioid epidemic in America. But this sleight of hand cannot hide Janssen's culpability in the current epidemic. While J&J and Janssen may not have successfully marketed their own opioid product, they nonetheless promoted use of opioids in general. And both reaped the benefits of those efforts.

Janssen seeks to avoid accountability for any damages in Summit and Cuyahoga counties by claiming that Duragesic, Nucynta and Nucynta ER account for a "minuscule sliver of the Track One market for opioid medications (between 0.1% and 0.9%) and an equally negligible share of doctor-shopping reports (0.13%)."[1] Janssen also erroneously asserts that its "unbranded marketing materials were not even published until years after Ohio had declared an opioid abuse crisis."[2] But neither argument absolves J&J and Janssen from liability.

In addition to its own branded, deceptive messaging, Janssen and its corporate parent, J&J, were at the heart of funding the third party "front group" pain advocacy organizations that

[1] *See* Janssen's MSJ at Dkt. # 1776-3 at p. 2.
[2] *Id.*

disseminated false messages about the undertreatment of pain in America, and provided misinformation about the low abuse potential of opioid products. Not only did Janssen and J&J fund such third party false marketing efforts; they actively participated in the creation of the false messaging itself. J&J and Janssen's unbranded and false marketing efforts began in the 1990s and continued throughout the past 20+ years. At a minimum, the impact of Janssen's more than 20 years of deceptive opioid promotion is a question of fact that cannot be resolved on summary judgment.

Janssen has also falsely claimed that false marketing messages propagated by Janssen and its strawman third party front groups are protected by the First Amendment.[3] This argument finds no support in the law. Both J&J and Janssen themselves and the front groups they funded were engaged in speech with a commercial purpose that is not constitutionally protected.[4]

J&J and Janssen funded front groups to increase their own opioid sales and to bolster the ***entire*** prescription opioid market. J&J literally owned nearly the entire opioid supply chain. J&J's subsidiary, Tasmanian Alkaloids, was responsible for growing alkaloid-rich poppy plants, which permitted J&J's Tasmanian Alkaloids to become the leading exporter of thebaine into the United States. Meanwhile, Janssen's subsidiary, Noramco, imported thebaine (and other opiates) from its corporate sibling for conversion into Active Pharmaceutical Ingredients ("API") that are used to make oxycodone, oxymorphone, hydrocodone, hydromorphone, morphine, and codeine, among other opioids.[5] Collectively, J&J and Janssen controlled entities[6] that were the largest thebaine producer and the largest oxycodone API manufacturer, thus enabling OxyContin and its generics to

[3] *See* Janssen's MSJ at Dkt. # 1776-3 at p. 7.
[4] That commercial purpose was to ensure that opioids were more widely prescribed by overcoming the barriers that would restrain opioid prescriptions (i.e., convincing physicians to prescribe opioids despite their concerns while minimizing concerns about addiction raised by physicians and patients alike).
[5] *See e.g.*, Exh 1 – PPLPC051000272272 (Purdue's production of Noramco's "Overview prepared for the sale of Noramco World Wide Narcotics Franchise global product portfolio. . . .").
[6] Exh 2 – JAN-MS-03117079 at 03117112 (Stock and Asset Purchase Agreement for the sale of Noramco, dated June 30, 2016).

be over-supplied in the United States. J&J and Janssen had significant financial incentive to increase opioid use in America.[7]

Janssen also argues that its Suspicious Order Monitoring System ("SOMS") "has been inspected by more than a dozen separate diversion investigators from the Drug Enforcement Agency over the years and maintains a perfect compliance record."[8] This too is false. Janssen's SOMS was utterly deficient and failed to comply with the Controlled Substances Act, as more completely addressed in "Plaintiffs' Motion for Partial Summary Adjudication that Defendants Did Not Comply With Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them" (Corrected) ("CSA-Compliance"), which is incorporated herein by reference.[9] The inspections upon which Janssen relies did not cover SOM systems and therefore are irrelevant to the analysis.

II. ARGUMENT

A. Janssen Cannot Demonstrate that No Genuine Issue of Fact Exists

The moving party has the burden of showing that no genuine dispute exists as to any material fact. *Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party[.]" *Kolesar v. Allstate Ins. Co.*, No 1:19. CV 35, 2019 WL 2996047, at *2 (N.D. Ohio July 9, 2019) (Polster, J.) (citing *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015)). In making this determination, "the court must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (citing same). Courts do not weigh the evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual

[7] Exh 3 – PPLPC037000007677 ("Janssen called and has called others to try to help deal with this media blitz and protect the pain movement.").
[8] Defs Dkt. # 1776-3 at 2 (Janssen's MSJ).
[9] *See* Plaintiffs' CSA-Compliance Motion at Dkt. # 1924 (sealed).

disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (citing *Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)).

B. Janssen's Marketing Substantially Contributed To Causing the Opioid Abuse Crisis in Ohio

Plaintiffs are not required to demonstrate that a single physician prescribed a single opioid medication because of Janssen's – or any other Manufacturer Defendant's – alleged misrepresentations. Plaintiffs incorporate by reference their Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation ("Causation Opp.").[10] Similarly, Plaintiffs incorporate by reference their response to Defendants' argument that Plaintiffs' intended aggregate proof of causation – including, but not limited to, the analysis of their expert Meredith Rosenthal – cannot establish that the Manufacturer Defendants collectively, or Janssen specifically, caused any increase in opioid prescriptions in the relevant jurisdictions.[11] We address certain of Janssen's specific unavailing arguments below.

1. Janssen's Branded Marketing Substantially Contributed to the Opioid Abuse Crisis Irrespective of Janssen's Market Share In Ohio

Janssen argues that its branded marketing promoted only Janssen's medications, and that its Duragesic and Nucynta played no role in the opioid crisis because Janssen never captured a significant market share, as reflected by the ARCOS database.[12] Janssen further argues that Plaintiffs have no evidence that Duragesic or Nucynta were widely abused. Janssen's arguments are misplaced. That Janssen's efforts were unsuccessful in promoting ***its own products*** does not mean that Janssen did not successfully promote use of opioids ***as a class***.

[10] *See* PSJ2 Causation Opp. Br. to Defs Dkt. #s 1869, 1897 and 1941.
[11] *Id.; see also* PD7 (Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude Meredith Rosenthal's Opinions and Proposed Testimony)("Rosenthal Opp.").
[12] *See* Dkt. # 1776-3 at p. 2.

2. Discovery Deposition Testimony Shows That Janssen's Opioid Products Were Widely Abused in Summit and Cuyahoga Counties

Janssen argues there is no evidence that Duragesic or Nucynta were widely abused, but it misleadingly omits deposition testimony of multiple bellwether county employees who *personally* witnessed and addressed the impact of fentanyl patches, including, specifically, Janssen's Duragesic patch, on or in the bodies of deceased overdose victims. For example, Steve Perch, the Summit County Medical Examiner, testified:

> A. I would certainly say the last three or four [years have been associated with illicit fentanyl]. Prior to that, actually, you know, we saw quite a bit of prescription Fentanyl in terms of the patches.
>
> Q. Okay.
>
> A. I don't know how many times we saw -- and Dr. Sterbenz would be the best, or Dr. Kohler, but numerous times -- and they would give me a heads-up -- we saw several patches on this guy or they'd find it in their gut. **You know, people were licking it or eating it, so we would find the actual Duragesic patch in their gut. So I saw quite a few of those.**[13]

Summit County's Chief Investigator, Gary Guenther, testified:

> Q. When -- in your experience, when did fentanyl start to show up in drug overdose autopsy investigations?
> MS. HERMIZ: Objection to form.
>
> A. I think we've always had, like I said, and I've seen cases from years and years ago where, you know, they do an autopsy and find a fentanyl patch that the person chewed or find somebody dead at the scene that's got the patch still in their mouth, you know. I want to say I'm sure those cases were fentanyl overdoses. But it really started becoming, you know –
>
> Q. In this 2013, '14, '15, '16 time frame?
> A. Yes. I mean, it's not like we never had them prior to those years. We've had them before, but I can't give you the numbers.[14]

Summit County's Chief Counsel, Brad Gessner, testified:

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[13] Steve Perch Dep. (10/18/2018), Dkt. # 1969-5 at 190:3-16 (emphasis added).
[14] Exh 4 – Gary Guenther Dep. (10/16/2018) at 324:21–325:12.

> Q. And what's your understanding about how potent fentanyl is relative to heroin or other drugs?
>
> A. The first I ever knew of fentanyl was when some of our investigators in the county were talking about an individual who had a time release fentanyl patch and they decided it wasn't working quick enough so they started chewing on it and died as a result of that.[15]

The deposition testimony of these county officials demonstrates that the Plaintiffs' employees observed and dealt with the consequences of widespread opioid abuse emanating from the J&J and Janssen's products, including, specifically, Janssen's Duragesic fentanyl patch.

3. Janssen Ignores Data That Shows Its Opioid Products Were Being Abused and Selectively Relies Upon Flawed Data

Janssen knew that Duragesic's abuse potential was substantial. In 2001, Janssen's VP of Pain, Steve Zollo, acknowledged that, "[a]s the use of Duragesic continues to rise (which it will), so will drug abusers trying to find creative ways to extract fentanyl from the patch. That's why it's a scheduled drug. As our use goes up, so will published reports of abuse."[16] In 2003, Janssen hired the Sacoor Medical Group to study and define "Relative Abuse Liability." Sacoor produced its results to Janssen, stating, in part:

> One of the issues is that Janssen's assumption is that fentanyl in a matrix patch could be a public health and social problem. And that's what Janssen should sensitize the FDA to…the reason Janssen haven't made a plain patch is because the Company thinks it's going to be a public health problem…abusers could just extract it and they can shoot it up. Moreover, if one just had the fentanyl in the matrix alone, it would be easier to divert. That's where Janssen should start from. The Company does not want another OxyContin, and its contention is that another patch without the naltrexone could be another OxyContin. That's really Janssen's argument. It starts from the same place. Then if you add naltrexone, you're going to reduce the abuse liability. **From 2001 to 2002, the numbers show that fentanyl is on the rise and, unfortunately, abusers of the reservoir patch who experiment and in many cases overdose,**

[15] Brad Gessner Dep. (12/3/2018), Dkt. # 1962-9 at 53:15–23; *see also* Exh 5 – George Sterbenz, M.D. Dep. (10/17/2018) at 67:4-18.
[16] Exh 6 – JAN-MS-00287030 at 00287031.

> **sometimes die. Duragesic has been very safe historically, but in the future it might not be as safe – say over the next two years. Particularly when one looks at the enormous amount of Duragesic that's on the market compared to ten years ago.**[17]

Independent of the Sacoor Medical Group's prediction, Janssen was tracking the Ohio Substance Abuse Monitoring Network and produced a report from Ohio in this case covering June 2002 through January 2003. The Ohio Substance Abuse report provided five conclusions at the end of the 122 page report. One of those five conclusions, stated, "[a]buse of fentanyl transdermal patches in the white population and cough syrups in the Black population seem to be new drug trends on the horizon."[18] Notably, Janssen's Duragesic transdermal fentanyl patch was the ***only transdermal fentanyl patch*** on the market at this date – as the patent did not expire until years later.

Janssen officials also expressed a dismissive attitude toward reports of diversion and abuse, even mocking public reports of abuse of fentanyl patches. In January 2006, Janssen executives distributed a news article describing how addicts were extracting fentanyl from prescription patches by boiling the patches in water. Bruce Ritchie, the former Duragesic Product Director, commented: "Very interesting – anyone for tea?" Gary Vorsanger, then Janssen's Senior Director of Analgesia, responded: "Are there antioxidants in Duragesic?"[19]

Nevertheless, to support the proposition that Duragesic ranked low in abuse risk, Janssen and its expert, Steven P. Cohen, M.D., solely and misleadingly cited *one* study from 2006.[20] That study merely surveyed 144 volunteers, including "casual users, substance abuse clients, pain patients, impaired professionals, and opioid and substance abuse experts."[21] Notably, the study concludes

[17] Exh 7 – JAN-MS-02105453 at 02105628 (Page 171 of 171) (emphasis added).
[18] Exh 8 – JAN-MS-02379190 at 02379308.
[19] Exh 9 – JAN-MS-02108736.
[20] *See* Defs Dkt. # 1776-11 at Cohen Dec. Exh A (*citing* Butler et al. *Harm Reduct* J 2006).
[21] *See* https://harmreductionjournal.biomedcentral.com/articles/10.1186/1477-7517-3-5 (emphasis added).

with a statement on "competing interests," advising: "This study was supported by Janssen Pharmaceutica."[22] Neither Janssen nor its expert advised the Court of this conflict of interest.

Similarly, to support the proposition that Nucynta ranked low in abuse risk, Janssen cited to self-serving deposition testimony of its own executives, Dr. Bruce Moskovitz and Dr. Gary Vorsanger, in which such employees cited to RADARS abuse data observed by Janssen.[23] However, Dr. Vorsanger addressed that the RADARS data was not useful in assessing misuse and abuse concerning Nucynta, stating:

> our initial thinking was that an analysis of RADARS monthly Nucynta PCC data would be useful as a tool to assess misuse and abuse early in the period after launch. However, methodologically, this has turned out to be more difficult that [sic] initially envisioned. After a number of discussions both internally and with RADARS, we are not comfortable that the analysis approach we have come up with will accomplish our aims, provide added value, and not produce misleading signals.[24]

Janssen's motion for summary judgment fails where there is a "genuine dispute of material fact." Here, there are numerous issues of material fact concerning both the incidence of abuse of Janssen's products and the credibility, independence and reliability of the subscription-based RADARS data.[25]

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[22] *Id.*

[23] *See* Defs Dkt. # 1776-4 Cardelus Decl. at Exh 4 and Exh 5, respectively citing Bruce Moskovitz Dep. (1/9/2019), Dkt. # 1968-10 at 684:4-17 and Gary Vorsanger Dep. (1/17/2019) Dkt. # 1971-17 at 298:21–299:4.

[24] Exh 10 – JAN-MS-02209558; *see also* Exh 11 – Gary Vorsanger Dep. (12/6/2018) at 542:1-5 (addressing that RADARS originated as a proprietary surveillance service operated by Purdue). Additionally, RADARS is a paid subscription service of which Janssen is a subscriber. Janssen paid RADARS [redacted] from 2006 through 2012. *See* Exh 12 – JAN-MS-02102511 at p. 18 (subscription contract dated 5/3/2006); Exh 13 – JAN-MS-01461235 at p. 2 (subscription contract dated 1/2/2008); Exh 14 – JAN-MS-02668294 at p. 22 (subscription contract dated 5/21/2009); Exh 15 – JAN-MS-02279158 at p. 21 (subscription contract dated 4/5/2011); Exh 16 – JAN-MS-01437956 at p. 20 (subscription contract dated 2/16/2012); *see also* Exh 17 – JAN-MS-02320051 (Janssen employees concede in internal communications that, RADARS "collects data through surveys," (at slide 10/24) and that there are "inherent limitations of data analysis in some of the RADARS programs." (at slide 10/24)).

[25] Exh 18 – JAN-MS-02305199 (e-mail demonstrating that Rick Dart, the head of RADARS, communicated with Janssen's Gary Vorsanger to strategize RADARS' intention to push back against West Virginia's 2007 request for drug-specific opioid data and to "redirect [West Virginia's] interest to Total Opioids, rather than individual drug substances.").

4. Janssen's Branded Marketing of Duragesic Contributed to the Public Nuisance of the Opioid Epidemic In Ohio, the Counties of Summit and Cuyahoga, and, Nationwide

Janssen's branded marketing of its Duragesic fentanyl patch significantly contributed to the opioid abuse crisis in Ohio, the counties of Summit and Cuyahoga, and nationwide. Rather than restate the history of Janssen's branded Duragesic marketing campaign, Plaintiffs incorporate by reference the Expert Report of David Kessler, M.D., and all exhibits cited in the Report's accompanying Schedules, which extensively addresses Janssen's marketing of Duragesic for non-malignant chronic pain, and Janssen's misleading marketing that Duragesic has no abuse potential, or, a lower abuse potential compared with OxyContin,[26] in addition to a litany of Janssen's deceptive tactics to grow prescriptions of Duragesic.

When Duragesic hit the market in 1991, it was initially intended for cancer patients. By October 2000, Janssen expanded its target patient base from cancer patients to individuals in pain who seek to "return[ ] to a more normal life as a patient benefit since 72 hour dosing and less breakthrough pain all for fewer interruptions."[27] It was at this time that Janssen began to "refresh" its advertising for Duragesic through the tagline: "Work, uninterrupted"[28] and "Chronic pain relief that improves physical and social functioning"[29] and Janssen addressed its goal to "Expand DURAGESIC® Use in Non-Malignant Pain," citing tactics, including: Direct Mail; Dinner Meetings; Symposia of APS and AAMP; Direct to Consumer Advertising.[30] As demonstrated below, Janssen's marketing was false and resulted in multiple rebukes by the FDA.

While Janssen sought to expand prescriptions of Duragesic from patients with cancer to patients experiencing chronic pain, Janssen simultaneously falsely promoted Duragesic as having no

[26] Report of David Kessler, MD, Dkt. # 2000-8 at ¶¶ 266–402 (addressing Duragesic).
[27] Exh 19 – JAN-MS-00309606 at slide 7/18 ("Duragesic Ad Campaign Overview").
[28] *Id.* at slide 15/18 ("Concept Development").
[29] *Id.* (depicting a baker kneading dough, whose work is uninterrupted due to the fentanyl patch).
[30] *See* Exh 20 – JAN-MS-00615319 at slide 23/52.

or lower abuse potential, in particular, as compared with OxyContin, without substantial evidence.[31] Indeed, Janssen's misrepresentations resulted in the issuance of three warning letters from the FDA: (1) a March 1998 letter chastising Janssen for promoting Duragesic as "recommended for use in chronic pain" without appropriate limiting language;[32] (2) a March 2000 letter criticizing a promotional piece that proclaimed "It's not just for end stage cancer anymore!;"[33] and (3) a September 2004 letter finding that Janssen had made "unsubstantiated effectiveness claims" that constituted "serious" violations.[34]

5. Janssen's Branded Marketing of Nucynta IR and ER Contributed to the Public Nuisance of the Opioid Epidemic In Ohio, the Counties of Summit and Cuyahoga, and, Nationwide

Janssen's branded marketing of its Nucynta products significantly contributed to the opioid abuse crisis in Ohio, the counties of Summit and Cuyahoga, and nationwide. Plaintiffs again incorporate by reference the Expert Report of David Kessler, M.D.,[35] and all exhibits cited in the Report's accompanying Schedules, which extensively addresses Janssen's misleading marketing campaign concerning Nucynta IR and Nucynta ER for the treatment of non-malignant chronic pain.[36]

For the Nucynta ER launch, Janssen paid Quintiles more than [redacted][37] to provide a contract sales force, consisting of [redacted] territory representatives, [redacted] district managers, and one national leader. Janssen directed its "Pain Force" to focus on high opioid prescribers in "launch-friendly states," based on IMS data and other metrics.[38] Janssen's former head of Nucynta sales and

[31] *See, e.g.,* Exh 21 – JAN-OH-00000004 (call notes promoting Duragesic as having "no abuse potential" or low risk of abuse).
[32] Exh 22 – JAN-MS-00238335.
[33] Exh 23 – JAN-MS-00238346.
[34] Exh 24 – JAN-MS-02530972.
[35] Kessler Rep., Dkt. # 2000-8.
[36] *Id.* at ¶¶ 403-460 (specifically addressing Nucynta).
[37] Exh 25 – JAN-MS-00576727 (David Lin Dep. Exh 11 – Dec. 2012 contract between Janssen and Quintiles for Janssen to pay [redacted] [redacted] in year 1 and [redacted] in year 2)).
[38] Exh 26 – JAN-MS-00660589 at slide 30/33 (David Lin Dep. Exh 13).

marketing, David Lin, testified, Janssen created a color-coded map that identified "areas of greater intensity of focus where Janssen was dedicating its Nucynta pain force sales representatives."[39] Ohio was 1 of 4 states in the nation that was prominently targeted by Janssen's marketing efforts at the launch of Nucynta because Janssen targeted areas where "there was a population of treaters of pain."[40] Tellingly, the patients were not Janssen's intended "customer." The prescribers were.[41] And Janssen spared no expense in its marketing efforts. Indeed, when Janssen spotted a high-prescribing physician in Cleveland, Ohio, who had prescribed 558 Opana ER prescriptions over the prior 13 week period, *but had written zero Nucynta prescriptions*, Janssen flew out a marketing executive from Janssen's New Jersey headquarters to Cleveland to meet with the prescriber and an Ohio district sales manager and convince the prescriber to write Nucynta ER prescriptions. Mr. Lin, testified, "the end game is to drive awareness of your product with a *customer* that is using long-acting opioids."[42]

One of Janssen's key Nucynta marketing themes, nationally and in Ohio, concerned its claim that Nucynta was associated with a low abuse potential. For example, on October 7, 2009, a Janssen employee provided a "clinical presentation" at the Ohio Department of Jobs and Family Services ("ODJFS") Pharmacy & Therapeutics ("P&T") Committee meeting, and addressed that Nucynta has fewer side effects than traditional opioids. When asked by a physician about Nucynta's addiction potential, the Janssen employee stated that there is the potential for addiction, but that Nucynta has less opioid activity than traditional opioids.[43] Although that claim was impermissible and off-label,[44] it was precisely the message Janssen intended that physicians would learn and recall. Two years later,

[39] Exh 27 – David Lin Dep. (12/20/2018) at 277:13–18.
[40] *Id.* at 236:23–237:17.
[41] *See id.* at 58:8-20; 97:7-14; 98:12-24; 217:10–218:14; 228:16–229:9; 258:13– 259:9; 262:15–263:18.
[42] Exh 28 – JAN-MS-00289532 (Lin Dep. Exh 12) (emphasis added).
[43] Exh 29 – Mary Applegate Dep. (03/28/19) at 331:17-332:12 (Mary S. Applegate, MD, is the Medical Director of Ohio Medicaid); Exh 30 (Applegate Dep. Exh 9); Exh 31 (Applegate Dep. Exh 10).
[44] *Supra* Exh 29 (Applegate Dep. at 334:11–336:23).

the ODJFS P&T Committee approved Nucynta's preferred formulary status, with one physician declaring that Nucynta was associated with less diversion compared to other opioids.[45]

Janssen even went so far as to retain PSI Pharmastrat, Inc., and others, to survey physicians and determine the impact of its Nucynta marketing campaign on physicians who wrote Nucynta prescriptions.[46] 76 percent of the surveyed physicians recalled seeing a Nucynta advertisement. Importantly, Janssen specifically studied physicians' most often recalled "attributes" of Nucynta, which included some of Janssen's core false marketing messages concerning: (1) "Unique Dual Mechanism of Action" (which could not be touted by Janssen without the FDA's required caveat statement that the "exact mechanism of action is unknown"); and (2) Decreased Abuse Potential (Janssen had no FDA approval to make this claim).[47] Janssen pushed its claimed "dual MOA" vigorously because it provided a scientific basis (*albeit unproven*) to claim that Nucynta "would be less attractive to someone who is looking to abuse or misuse the drug."[48]

Janssen even brazenly included erroneous statements about Nucynta in its Motion for Summary Judgment, stating, "[a]buse rates for Nucynta and Nucynta ER, *which contained an active ingredient designed to be abuse-deterrent*, were likewise much lower than for other opioid pills."[49] However, Janssen *never* received an Abuse Deterrent or "tamper-resistant" designation from the FDA for Nucynta.[50] In 2013, Janssen sought a tamper resistant formula ("TRF") labeling change from the FDA, claiming that Nucynta's post-marketing data demonstrated the drug was associated with a "low rate of abuse." The FDA rebuked Janssen and raised numerous questions concerning Janssen's low-abuse claims.[51]

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[45] *Id.* at 332:20-333:22; *see also supra* Exh 30 (Applegate Dep Exh 9).
[46] Exh 32 – JAN00015164.
[47] *Id.* at slide 10/108.
[48] Bruce Moskovitz, MD Dep. (11/14/18), Dkt. # 1968-11 at 674:15-20.
[49] Defs Dkt. # 1776-3 at 4 (Janssen's MSJ) (emphasis added).
[50] Exh 33 – Kanitha Burns Dep. (11/29/18) at 373:16 – 374:11; *see also* Exh 34 – JAN-MS-02385924 (evaluating opportunity to seek label change for abuse-deterrent formula).
[51] Exh 35 – JAN-MS-02043301 at 6-7 (FDA Preliminary Meeting Comments, August 5, 2013).

Regardless, Janssen repeatedly engaged in branded marketing efforts to address Nucynta's "low perceived addiction and/or abuse potential."[52] Janssen understated the risk of abuse by seeking to differentiate its drug as having lower abuse and withdrawal, compared to its competitors, without substantial evidence, and by understating the risk of addiction from opioids in its unbranded advertising. In Janssen's 2012 Nucynta and Nucynta ER Business Plan, Janssen laid out a marketing strategy to "generate data to support lower abuse potential" in order to "strengthen differentiation and value through new & compelling evidence."[53] The 2012 Business Plan further identified "Lower Abuse Potential" as a "Strategic Driver."[54]

Unfortunately, Janssen was quite successful at its "end game" to drive awareness and use of opioids in America, and in Ohio. Thus, despite Janssen's branded sales figures, it is undeniable that Janssen dedicated intense resources to its branded marketing machine throughout the nation, and, specifically in Ohio, which helped lead to an increase in opioid prescriptions, generally.[55]

6. Janssen's Unbranded Marketing Contributed to the Public Nuisance of the Opioid Epidemic In Ohio, the Counties of Summit and Cuyahoga, and, Nationwide

Janssen argues that it "did not publish the challenged unbranded marketing materials until 2008—long after opioid abuse had become a crisis in Ohio." Even if that date were relevant—and it is not, *see infra* pp. 12-15,—Janssen's assertion is inaccurate. Janssen has a long history of unbranded promotion of opioids. Beginning in the 1990s, Janssen and its parent, J&J, began paying front groups and individual doctors, also known as Key Opinion Leaders ("KOLs"), millions of dollars to market to physicians and prospective patients concerning the undertreatment of pain and the need to prescribe opioids more broadly. This fueled the opioid epidemic. As shown in a Janssen production document that has been submitted to the U.S. Senate Finance Committee, between

[52] Exh 36 – JAN00008227 at 20/54.
[53] Exh 37 – JAN-MS-00010801 at 12, 42.
[54] *Id.* at 43, 44.
[55] PD7 Rosenthal Opp. Br. to Defs Dkt. # 1767.

1997-2012, Janssen paid at least $4,078,750 to front groups, and paid at least $327,546 to individual doctors.[56] Between 1997-2008, Janssen paid approximately $2,669,591 to front groups.[57] Some examples of Janssen's payments to front groups are:

- $1,793,906 to American Pain Society ("APS") (1997-2012)
- $562,674 to American Academy of Pain Medicine ("AAPM") (1997-2012)
- $515,244 to Joint Commission Resources (1997-2012) [58]

In turn, Janssen received unbranded marketing benefits from these entities. In 1997, APS and AAPM jointly published a guideline titled, "The Use of Opioids for the Treatment of Chronic Pain," which contained numerous misleading statements regarding the low abuse potential of opioid prescription drugs and the undertreatment of pain in society. Janssen used this guideline to promote opioid products and opioids, in general.[59]

APS and AAPM coordinated with the American Society of Addiction Medicine ("ASAM"), to develop the consensus "Definitions Related to the Use of Opioids for the Treatment of Pain," which contains the following misleading statement concerning pseudoaddiction: "An individual's behaviors that may suggest addiction sometimes are simply a reflection of unrelieved pain or other problems unrelated to addiction." Janssen utilized this concept of "pseudo addiction" in its marketing presentations.[60] Concurrently, in 2001, Janssen disseminated a Duragesic patient booklet, which claimed, "addiction is relatively rare when patients take opioids appropriately," and "[p]hysical

[56] Exh 38 – JAN-MS-00000001; *see also* Report of Matthew Perri, BS Pharm, PhD, Rph, Dkt. #'s 2000-19, 2000-20, and 2000-21 (addressing front group involvement in creating false and misleading messages that played a significant role in this opioid crisis, and citing to Janssen's funding of such front groups.); Exh 39 (Lin Dep. Exh 9 – JAN00119068); *supra* Exh 27 (Lin Dep. at 216:1–219:5) (testifying that Janssen paid at least $4 million to MedForce, a pass through agency, that, in turn, paid KOLs). Janssen also paid pass-thru agencies who paid KOLs.
[57] *Supra* Exh 38 – JAN-MS-00000001; Kessler Rep., Dkt. # 2000-8 at ¶¶ 581-589. Further, from 2012 to 2017, Janssen paid APS an additional $88,500 and Janssen paid AAPM an additional $83,975. *See* Kessler Rep., Dkt. # 2000-8 at ¶¶ 598-599.2 (citing Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, at pp. 4-5).
[58] *Supra* Exh 38 – JAN-MS-00000001.
[59] *See* Kessler Rep., Dkt. # 2000-8 at ¶¶ 586-589.
[60] Exh 40 – JAN-MS-00310473.

dependence is not the same as addiction. It is easily managed by gradually reducing dose of the drug."[61]

Additionally, J&J and Janssen, through the Robert Wood Johnson Foundation ("RWJF"),[62] funded the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"). Between 1997-2004, RWJF paid **$5,926,294.00** in grants to the University of Wisconsin-Madison School of Medicine, the eventual home of Janssen's favored front group, the Pain & Policy Studies Group ("PPSG").[63] JCAHO and PPSG created new pain treatment standards in 2001 that were favorable to the opioid manufacturing industry.[64] In 2001, Janssen paid $75,000 to the PPSG to help start the front group.[65] Thereafter, Janssen used the new JCAHO guidelines as part of its unbranded marketing campaign. Further, Janssen (and other opioid manufacturers) partnered with PPSG and other front groups, including AAPM and APS, to advocate for opioid-friendly prescribing guidelines throughout the nation.[66]

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[61] Exh 41 – JAN-MS-02757826 at 02757847 (Janssen's patient booklet cited the APS/AAPM/ASAM consensus definitions addressed above, as well as a publication by one of its premier KOLs, Dr. Portenoy.).

[62] J&J funded the RWJF with a grant of J&J stock. In 2017, RWJF reported holding $2 billion in J&J stock. *See* https://www.rwjf.org/content/dam/files/rwjf-web-files/Financials/FY2017-RobertWoodJohnsonFdn-FS.pdf.

[63] Exh 42 – Carla Cartwright Dep. (1/17/19) at 91:12–98:20; *see also* Exh 43 – MDL_RWJF_0000001: Grant ID 032037 for $1,601,991 (through this grant, RWJF affected 2001 change in JCAHO pain treatment standards/guidelines – the first guidelines that would hold physicians/facilities accountable for failure to treat pain). RWJF also funded the creation and dissemination of the Model State Guidelines through the Federation of State Medical Boards and its collaboration with the PPSG. *See e.g.*, Exh 44 – MDL_RWJF_0000003: Grant ID 036509 for $998,000 (grant from RWJF to University of Wisconsin-Madison Medical School for the term of August 1999 through April 2002. The grant project is "[a] project to assess states' pain policies" as part of RWJF's Targeted End-of-Life Projects Initiative. *Id.* David Joranson is the project director. The grant states "the purpose of this project is to conduct the first state-by-state assessment of states' laws, regulations, and guidelines regarding the treatment of pain with controlled substances"); Exh 45 – MDL_RWJF_0000004: Grant ID 036547 for $998,865; Exh 46 – MDL_RWJF_0000005: Grant ID 037589 for $1,408,628; Exh 47 – MDL_RWJF_0000010: Grant ID 043940 for $421,800; Exh 48 – MDL_RWJF_0000009: Grant ID 043412 for $200,450; Exh 49 – MDL_RWJF_0000012: Grant ID 048204 for $183,680; Exh 50 – MDL_RWJF_0000013: Grant ID 051813 for $112,880.

[64] Exh 51 – JAN-MS-00078232 ("Pain: Current Understanding of Assessment, Management, and Treatments," dated Dec. 2001).

[65] Exh 52 - JAN-MS-00313716.

[66] Exh 53 - JAN-MS-00368809 at slides 14, 15; *see also* slide 11 (ranking all states in the nation with letter grades based upon "Pain Policy Scores from Pain & Policy Studies Group"); *see supra* Exh 44 - MDL_RWJF_0000003; *see also* Exh 54 - CHI_000445270 at 000445272; Joel R. Saper, M.D., Dep. (01/11/19), Dkt. # 1970-15 at 47:16–49:3; Exh 55 (Saper Dep. Exh 3 (July 1, 2008 Resignation Letter of Joel R. Saper, M.D., sent to presidents of APS and AAPM)).

Janssen also paid KOLs to misleadingly advocate for liberal opioid prescribing guidelines and to influence other doctors through "peer to peer education."[67] As early as March 2001, Janssen reached out to Russell Portenoy, M.D., a major KOL, as reflected in a document indicating that "[Dr. Portenoy] said that Janssen called and has called others to try to help deal with this media blitz and ***protect the pain movement***."[68]

The evidence demonstrates that Janssen engaged in *pre*-2008 unbranded marketing. But, even if it were otherwise, Janssen erroneously contends that any *post*-2008 unbranded marketing would not have had an impact on Ohio's opioid crisis, because such marketing occurred "well after Ohio's opioid crisis was already underway."[69] For evidence that post-2008 marketing efforts contributed to the growth of the opioid crisis, this Court need look no further than to Janssen's 2011 efforts to specifically target children through "Media Outreach Initiatives" for the purposes of "Reaching out to: Youth," and "Reach early: elementary school level; via respected channels, e.g., coaches," to "Deliver a practical message: Pain is your body telling you something important."[70] The evidence at trial will demonstrate that the opioid crisis continued to grow well past 2010, and Janssen's post-2008 marketing worsened the crisis.

C. False and Misleading Statements That Janssen and Its Surrogates Propagated About Janssen's Opioid Products Are Not Protected Under the First Amendment

Janssen argues that it cannot be held accountable for speech that is protected by the First Amendment, ignoring Supreme Court precedent. It is well-settled that, "[u]ntruthful speech, commercial or otherwise, has never been protected for its own sake." *Va. State Bd. Of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976). "For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading." *Central*

[67] *Supra* Exh 36 – JAN00008227 at slides 5/54, 11/54, and 15/54.
[68] *See supra* Exh 3 – PPLPC037000007677 (emphasis added).
[69] Defs Dkt. # 1776-3 at 3 (Janssen's MSJ).
[70] Exh 56 – JAN-MS-00393295 at slide 3/7; *see also supra* Exh 11 – Gary Vorsanger, MD Dep. (12/5-6/18) at 674-675.

Hudson Gas & Elec. Corp. v. Public Service Commission of New York, 447 U.S. 557, 566 (1980) (emphasis added). Janssen's unbranded marketing activities were most definitely misleading, and thus not entitled to First Amendment protection.

In its Motion for Summary Judgment, Janssen cites cases involving First Amendment protection of "works which, taken as a whole, have serious literary, artistic, political, or scientific value, regardless of whether the government or a majority of the people approve of the ideas these works represent," (*Miller v. California*, 413 U.S. 15, 34 (1973)), protection of a research university from having to abide by an overbroad, vague confidentiality clause on a government contract (*Bd. Of Trustees of Leland Stanford Jr. Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991), protection of "statements [that] were entitled to First Amendment protection because those statements were on matters of public concern, were not provably false, and were expressed solely through hyperbolic rhetoric," (*Snyder v. Phelps*, 562 U.S. 443, 451 (2011)), and protection of selling indisputably true factual data (*Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011)).

None of the cases Janssen cites support its position that so-called "Third-Party Speech" about its opioid products is protected by the First Amendment. In contrast, the above cases all support that Janssen's Motion for Summary Judgment is inappropriate and that there is at least a genuine dispute of material fact as to whether:

(1) the so-called "Third-Party Speech" at issue is of a public interest, as Janssen argues, or, whether it is "commercial speech," aided by J&J's and Janssen's marketing efforts and disseminated by Janssen-supported Front Groups, such as, the American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS"), and by Janssen-paid Key Opinion Leaders, at the behest of Janssen; and

(2) the so-called "Third-Party Speech" is truthful, as we presume Janssen contends, or, whether it is false and misleading, as Plaintiffs argue and is supported by the evidence, fact witness testimony, and expert witness testimony.

Because there is at least a genuine dispute of material fact as to whether Janssen's so-called "Third-Party Speech" is protected by the First Amendment, Summary Judgment on this issue is inappropriate.

D. Plaintiffs' Diversion Theory Supports Their Claims

Janssen asserts that, (i) its Suspicious Order Monitoring System ("SOMS") was adequate, (ii) the fact that DEA investigated Janssen's SOMS but never sanctioned Janssen is sufficient evidence of its adequacy, and, (iii) Plaintiffs must present individualized proof of diversion to defeat summary judgment. As shown below, all three arguments are not supported by the evidence and all three arguments are not supported by the law.

1. Janssen's Monitoring of Suspicious Orders Was Deficient

Janssen mistakenly takes the position that no reasonable jury could conclude that its suspicious order monitoring program was deficient. But the Court could reach such a conclusion only if it ignored that during the entire lifetime of Janssen's SOM program, which began in 2005,[71] Janssen never reported a suspicious order to the DEA[72] and **only** monitored for orders of unusual size for customers with a prior order history;[73] thus failing to ever monitor for frequency and/or pattern in real time.[74] Plaintiffs' expert Lacey Keller's report demonstrates that, had Janssen

[71] Exh 57 – JAN-MS-03741170; Exh 58 – JAN-MS-03741177; Exh 59 – JAN-MS-03741201.
[72] Exh 60 – JAN-MS-05444748 at 05444761 (Recommendation 13) (1/8/2018 Draft "Evaluation of the Suspicious Orders Monitoring System For Johnson & Johnson," by Terrance W. Woodworth, of The Drug & Chemical Advisory Group, LLC. This is an audit of J&J, Janssen, and JOM's (Janssen Ortho-McNeil's SOM program)).
[73] *Supra* Exh 57 - JAN-MS-03741170 at 03741172; Exh 61 – JAN-MS-03124101; *supra* Exh 60 – JAN-MS-05444748 at 05444757 (Recommendation 4a); Michele Dempsey Dep. (3/8/19), Dkt. # 1961-13 at 472:12–473:23.
[74] Exh 62 – JAN-MS-02983578 (on 1/23/18, Janssen's Director of Controlled Substance Compliance acknowledged that the algorithm "only measures quantity and does not consider frequency or pattern of ordering by the same customer"); Exh 63 – JAN-MS-05444730 ("The DEA guidelines include an expectation for us to flag: • Orders of unusual size[;] • Orders deviating substantially from normal pattern[;] • Orders of unusual frequency[.] We currently

instituted appropriate SOM policies, "prescriptions for millions of dosage units could have been stopped in Summit and Cuyahoga counties."[75] Janssen's SOM compliance was so arcane and deficient – for the entire lifetime of the "compliance" program – that Plaintiffs have separately moved for partial summary judgment *in their favor* concerning Janssen's CSA violations. Rather than restate all of the arguments previously briefed, Plaintiffs incorporate by reference the relevant portion of Plaintiffs' CSA-Compliance motion concerning Janssen.[76]

2. DEA's Non-Censure of Janssen Following Inspections of Janssen's Facilities Is Not Evidence That Janssen Had an Adequate Suspicious Order Monitoring System

Janssen argues that "[t]he undisputed facts show that Janssen diligently monitored suspicious orders and that the DEA never called into question Janssen's compliance with the CSA." *See* Dkt. #1776-3 (Janssen MSJ) at p. 9. Janssen further touts, "None of the DEA's many inspections revealed a single failure or deficiency in Janssen's suspicious order monitoring." *Id.* at p. 10.

Janssen's claim that DEA's non-censure proves its SOMS was adequate, must be rejected. In *Masters Pharm., Inc. v. Drug Enforcement Admin.*, 861 F.3d 206, 224-25 (D.C. Cir. 2017), the D.C. Circuit Court addressed and rejected a more persuasive version of Janssen's argument. Masters challenged DEA's revocation of its certificate of registration, arguing, in part, that the revocation was unwarranted because, prior to the revocation, the DEA was required to visit Masters' 'distribution center' and "conduct a review of the functionality of Master[s]' diversion compliance program' (the Compliance Review)." *Id.* at 24. After DEA conducted the Compliance Review, ". . . Masters did not receive the written notice that DEA promised to provide if it found the

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have a process to flag unusual based on list 1 chemicals and is not up to current industry practice. The other two requirements are vulnerabilities that must be addressed. Our current monitoring program flags orders of unusual size (a running average of past orders is taken and we flag any order that is 300% more than average). We do not currently account for ordering frequency or cumulative effect of multiple orders in one month against a threshold[.]"); Dempsey Dep., Dkt. # 1961-13 at 472:19–473:18 ("Q:…. I said this algorithm only measures quantity and does not consider frequency or a pattern of ordering by the same customer. Do you agree with that? A: That is what the algorithm does, the quantity. Q: And so you agree with that, right? Yes? A: Yes.").

[75] Report of Lacey Keller, Dkt. # 2000-7 at ¶ 34.

[76] *See* Plaintiffs' CSA-Compliance Motion (Dkt. # 1924 sealed).

Compliance Review to be 'not satisfactory,'. . . and because of 'DEA's silence following the Compliance Review,' Masters says that it presumed that it was operating within the letter of the law." *Id.* at 224. Based on the Compliance Review and DEA's subsequent silence, Masters argued that DEA was "equitably estopped from holding Masters responsible for any deficiencies in the SOMS of which the agency did not previously notify Masters in writing." *Id.*

The D.C. Circuit Court ultimately rejected Masters' reliance and equitable estoppel arguments for several cogent reasons, and, significantly, opined that DEA's investigators' mere paper review of Masters' SOMS, and DEA's subsequent non-censure of Masters, could not be relied upon by Masters as evidence its SOMS was adequate.[77]

The *Masters* decision refutes Janssen's boast that prior DEA inspections can be used as evidence of adequate SOMS because "[n]one of the DEA's many inspections revealed a single failure or deficiency in Janssen's suspicious order monitoring." Moreover, as Janssen is well aware, prior to any of the DEA inspections, in 2007 Janssen had been put on notice by the DEA that, "past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."[78] DEA reiterated this message on June 12, 2012.[79] In light of this clear authority, Janssen should not be permitted to claim that DEA's non-censure, following site inspections (in which the DEA's "primary" inspection objectives were unrelated to SOMS), is evidence that the DEA blessed Janssen's woefully inadequate SOMS, which resulted in Janssen's failure to ever report even a single suspicious order to the DEA during the life of Janssen's purported monitoring program.

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[77] *Id.* at 225 (stating, "The most DEA's Diversion Investigators were in a position to do is comment on the adequacy of the SOMS Compliance Protocol on paper.").
[78] Exh 64 – JAN-MS-02960654 at 02960712 (December 27, 2007 letter to all registered manufacturers and distributors of controlled substances, by DEA Deputy Assistant Administrator Joseph T. Rannazzisi) (Dempsey Dep. Exh 25).
[79] Exh 65 – ABDCMDL00003659 (June 12, 2012 letter to all registered manufacturers of controlled substances, by DEA Depute Assistant Administrator Joseph T. Rannazzisi).

3. Plaintiffs Do Not Need to Present Individualized Proof of Diversion to Defeat Summary Judgment

Plaintiffs separately filed an Opposition to Manufacturer Defendants' Motion for Summary Judgment on Causation. In that Opposition, Plaintiffs argue that each Manufacturer Defendant, through a deceptive and illegal marketing campaign and a failure to prevent diversion of its prescription opioids, caused sharply increased harms and costs from both licit and illicit opioid use in the Plaintiff Counties. Plaintiffs demonstrate this causal connection with both statistical analysis of aggregate evidence by prominent public health economists and more individuated proof that each Manufacturer Defendant's intentional and negligent conduct was expected to and did cause these extensive harms. Plaintiffs incorporate those arguments herein by reference.[80]

III. CONCLUSION

Janssen is not entitled to summary judgment concerning its unbranded and branded marketing defenses, its specious First Amendment arguments, or its claim that it had a purportedly perfect regulatory compliance program. There are genuine disputes of material fact concerning each of Janssen's purported defenses to Plaintiffs' claims and, therefore, Janssen's motion should be denied.

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